MAY 2 2 2014
K140373

510(k) Summary, cobas 8000 ISE Calibration Change and Measuring Range Extension

Continued on next page

510(k) Summary: cobas 8000 ISE Calibration Change and Measuring Range Extension, *continued*

Introduction

The information in this 510(k) summary is being submitted in accordance with requirements of 21 CFR 807.92.

Submitter name, address, and contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Contact person: David Tribbett
Phone: 317-521-2964
Fax: 317-521-2324

Date Prepared: May 8, 2014

Device name

Proprietary name:	cobas 8000 ISE Indirect Na, K, Cl for Gen. 2.
Common name:	Sodium Test System Potassium Test System Chloride Test System
Classification:	Ion-Specific Electrode Sodium Ion-Specific Electrode Potassium Ion-Specific Electrode Chloride

Establishment registration

For the cobas 8000 ISE module, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics, United States is 1823260.

Continued on next page

510(k) Summary: cobas 8000 ISE Calibration Change and Measuring Range Extension, *continued*

Classification

The FDA has classified the Sodium, Potassium, and Chloride Test Systems as Class II devices.

Panel	Product Code	Classification Name	Regulation
Clinical Chemistry (75)	JGS	Ion Specific Electrode, Sodium	21 CFR 862.1665
Clinical Chemistry (75)	CEM	Ion Specific Electrode, Potassium	21 CFR 862.1600
Clinical Chemistry (75)	CGZ	Ion Specific Electrode, Chloride	21 CFR 862.1170

Proposed labeling

Draft labeling sufficient to describe the device, its intended use, and the directions for use on the **cobas** 8000 ISE analyzer module for serum, plasma, and urine samples is included in the submission.

Device description

The cobas 8000 ISE module is an Ion-Selective Electrode (ISE) system for the determination of sodium, potassium, and chloride in serum, plasma, and urine. The cobas 8000 ISE module and the ISE Gen 2 reagents were previously cleared for serum and plasma sample types under K100853 and urine sample type on K123726.

This premarket notification seeks to obtain FDA review and clearance for the **urine sample type** for the ISE Gen 2 reagents on the cobas 8000 ISE module using an expanded measuring range for sodium and chloride analytes at the low end of the measuring range and the new calibration method cleared in K132418.

An ISE makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions will closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The EMF develops according to the Nernst equation for a specific ion in solution (see package insert for further explanation). Please refer to K100853 for detailed hardware and software information relating to the cobas 8000 modular analyzer series.

Commercially available controls are recommended for the urine sample type. Aqueous ISE standards Low and High were cleared under K053165. The LHH calibration scheme was cleared under K132418.

510(k) Summary: cobas 8000 ISE Calibration Change and Measuring Range Extension, *continued*

Intended use

The ISE module of the Roche/Hitachi **cobas c** system is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes.

Indications for use

The cobas 8000 ISE module is a fully automated ion-specific analyzer intended for the in vitro potentiometric determination of chloride, potassium, and sodium in serum, plasma, and urine using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

Substantial equivalence - comparison

The following tables compare the cobas 8000 ISE module using Low/High/High calibration and its predicate device the cobas 8000 ISE Module using Low/High/Serum Compensator calibration cleared under K123726.

Comparison of Systems – similarities and differences

System Comparison		
Parameter	**Predicate Device cobas 8000 ISE Module (K123726)**	**Candidate Device cobas 8000 ISE Module**
Intended use	The ISE module of the Roche/Hitachi cobas c systems is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes.	Same
Specimen Type	Serum/Plasma/Urine	Same
Measurement principle	ISE Potentiometry	Same
Reagent container	Plastic bottles closed via screw caps	Same
Onboard storage temperature	Room Temperature	Same
ISE Module	Separate ISE module connected to Core cobas 8000 module	Same
Ion Selective electrodes (ISEs)	Potentiometric chloride, potassium, sodium and reference electrodes	Same
Sample Dilution (Serum/plasma)	1:31	Same
Sample Dilution (Urine)	1:46 Standard Range	1:46 Standard Range 1:31 Under Range Rerun
Throughput	Max 1800 tests/hour	Same
Calibration Scheme	ISE Standard Low, High, Serum Compensator (LHSc)	ISE Standard Low, High, High (LHH)

Comparison of assays – similarities and differences

(Sodium)

Assay Comparison Sodium								
Parameter	**Predicate Device cobas 8000 Urine ISE LHSc Calibration Method (K123726)**				**Candidate Device cobas 8000 Urine ISE LHH Calibration Method**			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	66.4	0.4	0.6	Low	69.9	0.2	0.3
	Med	178.9	0.9	0.5	Med	174.5	0.5	0.3
	High	321.7	0.7	0.2	High	347.2	0.9	0.3
	Liq 1	81.1	0.3	0.4	Liq 1	83.4	0.3	0.3
	Liq 2	170.6	0.5	0.3	Liq 2	175.6	1.3	0.8
					Under Range Rerun using increased sample:			
					Low	24.7	0.2	0.9
					Med	37.7	0.2	0.6
					MDL	31.7	0.2	0.7
					High	56.8	0.4	0.6
					Liq 1 diluted	42.1	0.3	0.6
					Liq 2 diluted	32.2	0.3	0.8
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	68.6	1.1	1.6	Low	69.9	1.3	1.8
	Med	180.3	1.0	0.6	Med	174.5	1.1	0.7
	High	318.0	2.1	0.7	High	347.2	2.8	0.8
	Liq 1	82.7	1.2	1.4	Liq 1	83.4	1.3	1.6
	Liq 2	171.3	1.0	0.6	Liq 2	175.6	1.7	1.0
					Under Range Rerun using increased sample:			
					Low	24.7	0.9	3.7
					Med	37.7	1.0	2.7
					MDL	31.7	1.0	3.0
					High	56.8	1.1	1.9
					Liq 1 diluted	42.1	1.0	2.5
					Liq 2 diluted	32.2	1.0	3.9
Method Comparison to reference (flame photometer)	N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.976 Intercept (Bablok) = 4.3548 Range (X) = 65.7 - 327.7				N = 106 Days = 2 Correlation = 0.9995 Slope (Bablok) = 0.997 Intercept (Bablok) = 0.984 Range (X) = 69.2 - 337.4			
Method comparison to predicate	N = 59 Days = 2 Correlation = 0.9996 Slope (Bablok) = 0.930 Intercept (Bablok) = 12.0671 Range (X) = 63.8 - 339.2				N = 92 Days = 2 Correlation = 0.9999 Slope (Bablok) = 1.021 Intercept (Bablok) = -4.562 Range (X) = 65.3 – 342.1			
Detection Limits	LOB = 7.6 mmol/L LOD = 8.9 mmol/L LOQ = 23.2 mmol/L				LOB = 8.1 mmol/L LOD = 9.8 mmol/L LOQ = 15.5 mmol/L			
Standard Measuring range	60-350 mmol/L				60-350 mmol/L			
Under Range	No Extended Range				20-59.9 mmol/L via rerun with increase sample volume			

Comparison of assays – similarities and differences

(Potassium)

Assay Comparison Potassium								
Parameter	**Predicate Device cobas 8000 Urine ISE LHSc Calibration Method (K123726)**				**Candidate Device cobas 8000 Urine ISE LHH Calibration Method**			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	3.65	0.00	1.2	Low	3.47	0.01	0.3
	Med	51.10	0.30	0.6	Med	50.70	0.26	0.5
	High	83.78	0.66	0.8	High	93.48	0.58	0.6
	Liq 1	32.19	019	0.6	Liq 1	30.64	0.20	0.6
	Liq 2	69.47	0.39	0.6	Liq 2	66.22	0.61	0.9
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	3.75	0.06	1.7	Low	3.47	0.04	1.1
	Med	49.48	0.65	1.3	Med	50.70	0.63	1.2
	High	80.60	1.32	1.6	High	93.48	1.82	1.9
	Liq 1	31.32	0.37	1.2	Liq 1	30.64	0.32	1.0
	Liq 2	67.49	1.17	1.7	Liq 2	66.22	1.14	1.7
Method Comparison to reference (flame photometry)	N = 59 Days = 2 Correlation = 0.9993 Slope (Bablok) = 0.962 Intercept (Bablok) = 1.7605 Range (X) = 4.20 - 91.90				N = 99 Days = 2 Correlation = 0.9997 Slope (Bablok) = 1.014 Intercept (Bablok) = 0.507 Range (X) = 3.80 – 86.30			
Method comparison to predicate	N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.920 Intercept (Bablok) = 1.4589 Range (X) = 3.98 - 97.74				N = 92 Days = 2 Correlation = 0.9998 Slope (Bablok) = 1.021 Intercept (Bablok) = -0.208 Range (X) = 4.87 – 96.94			
Detection Limits	LOB = 0.3 mmol/L LOD = 0.4 mmol/L LOQ = 2.3 mmol/L				LoB = 0.3 mmol/L LoD = 0.4 mmol/L LoQ = 1.1 mmol/L			
Reportable range	3-100 mmol/L				3-100 mmol/L			
Extended Range	No Extended Range				No Extended Range			

Comparison of assays – similarities and differences

(Chloride)

Assay Comparison Chloride								
Parameter	**Predicate Device cobas 8000 Urine ISE LHSc Calibration Method (K123726)**				**Candidate Device cobas 8000 Urine ISE LHH Calibration Method**			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	63.6	0.5	0.7	Low	65.3	0.3	0.4
	Med	180.8	0.9	0.5	Med	167.6	0.5	0.3
	High	341.7	1.1	0.3	High	333.5	1.6	0.5
	Liq 1	92.3	0.4	0.5	Liq 1	97.5	0.5	0.5
	Liq 2	189.6	0.6	0.3	Liq 2	193.2	1.5	0.8
					Under Range Rerun using increased sample:			
					Low	21.6	0.2	1.0
					Med	34.2	0.3	0.9
					MDL	28.0	0.2	0.9
					High	55.0	0.4	0.8
					Liq 1 Diluted	43.7	0.3	0.7
					Liq 2 Diluted	29.0	0.4	1.5
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	64.7	1.1	1.7	Low	65.3	0.9	1.3
	Med	179.7	1.2	0.7	Med	167.6	1.1	0.7
	High	336.5	3.5	1.0	High	333.5	3.5	1.0
	Liq 1	92.6	1.1	1.2	Liq 1	97.5	0.9	0.9
	Liq 2	187.6	1.6	0.9	Liq 2	193.2	2.0	1.0
					Under Range Rerun using increased sample:			
					Low	21.6	0.8	3.7
					Med	34.2	0.9	2.5
					MDL	28.0	0.8	3.0
					High	55.0	0.9	1.7
					Liq 1 Diluted	43.7	1.0	2.3
					Liq 2 Diluted	29.0	0.9	3.2
Method Comparison to reference (coulometry)	N = 59 Days = 2 Correlation = 0.9985 Slope (Bablok) = 1.092 Intercept (Bablok) = -11.2893 Range (X) = 66.0 - 324.0				N = 100 Days = 2 Correlation = 0.9995 Slope (Bablok) = 1.029 Intercept (Bablok) = -3.996 Range (X) = 66.0 – 287.0			
Method comparison to predicate	N = 59 Days = 2 Correlation = 0.9997 Slope (Bablok) = 0.952 Intercept (Bablok) = 0.5078 Range (X) = 65.2 - 350.0				N = 92 Days = 2 Correlation = 0.9998 Slope (Bablok) = 1.023 Intercept (Bablok) = -3.284 Range (X) = 62.2 - 330.5			
Detection Limits	LOB = 8.7 mmol/L LOD = 9.7 mmol/L LOQ = 13.4 mmol/L				LOB = 7.8 mmol/L LOD = 9.0 mmol/L LOQ = 18.3 mmol/L			
Standard Measuring range	60-350 mmol/L				60-350 mmol/L			
Under Range	No Extended Range				20-59.9 mmol/L via rerun with increase sample volume			

Evaluations summary	The cobas 8000 ISE Module, Urine Sample Type was evaluated for several performance characteristics, including repeatability, intermediate precision, LoB, LoD, LoQ, method comparison, recovery in controls, and linearity.
Conclusion	The ISE Gen 2 reagents applied to the cobas 8000 ISE analyzer using LHH calibration and increased sample rerun mode is substantially equivalent to the predicate cobas 8000 ISE analyzer using LHSc calibration cleared under K123726.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

ROCHE DIAGNOSTICS
MR DAVID TRIBBETT
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K140373
Trade/Device Name: cobas 8000 ISE Indirect Na, K, Cl for Gen.2
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: II
Product Code: JGS, CEM, CGZ
Dated: May 8, 2014
Received: May 12, 2014

Dear Mr. David Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k140373

Device Name
cobas 8000 ISE Indirect Na, K, Cl for Gen. 2

Indications for Use *(Describe)*

The cobas 8000 ISE module is a fully automated ion-specific analyzer intended for the in vitro potentiometric determination of chloride, potassium, and sodium in serum, plasma, and urine using ion-selective electrodes. Measurements obtained by this device are used in the diagnosis and treatment of diseases or conditions involving electrolyte imbalance.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S